

# **ULTRA STRENGTH MUSCLE RUB- camphor, menthol, methyl salicylate cream**

## **The Mentholatum Company**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Drug Facts**

#### **Active ingredients**

Camphor 4%

Menthol 10%

Methyl salicylate 30%

#### **Purpose**

Camphor - Topical analgesic

Menthol - Topical analgesic

Methyl salicylate - Topical analgesic

#### **Uses**

temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

#### **Warnings**

**For external use only**

#### **When using this product**

- use only as directed
- do not get into eyes or on mucous membranes
- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with a heating pad or apply external heat

#### **Stop use and ask a doctor if**

- skin redness or excessive irritation of the skin occurs
- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few

days

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- adults and children 12 years and over: apply to affected area not more than 3 to 4 times daily
- children under 12 years: ask a doctor

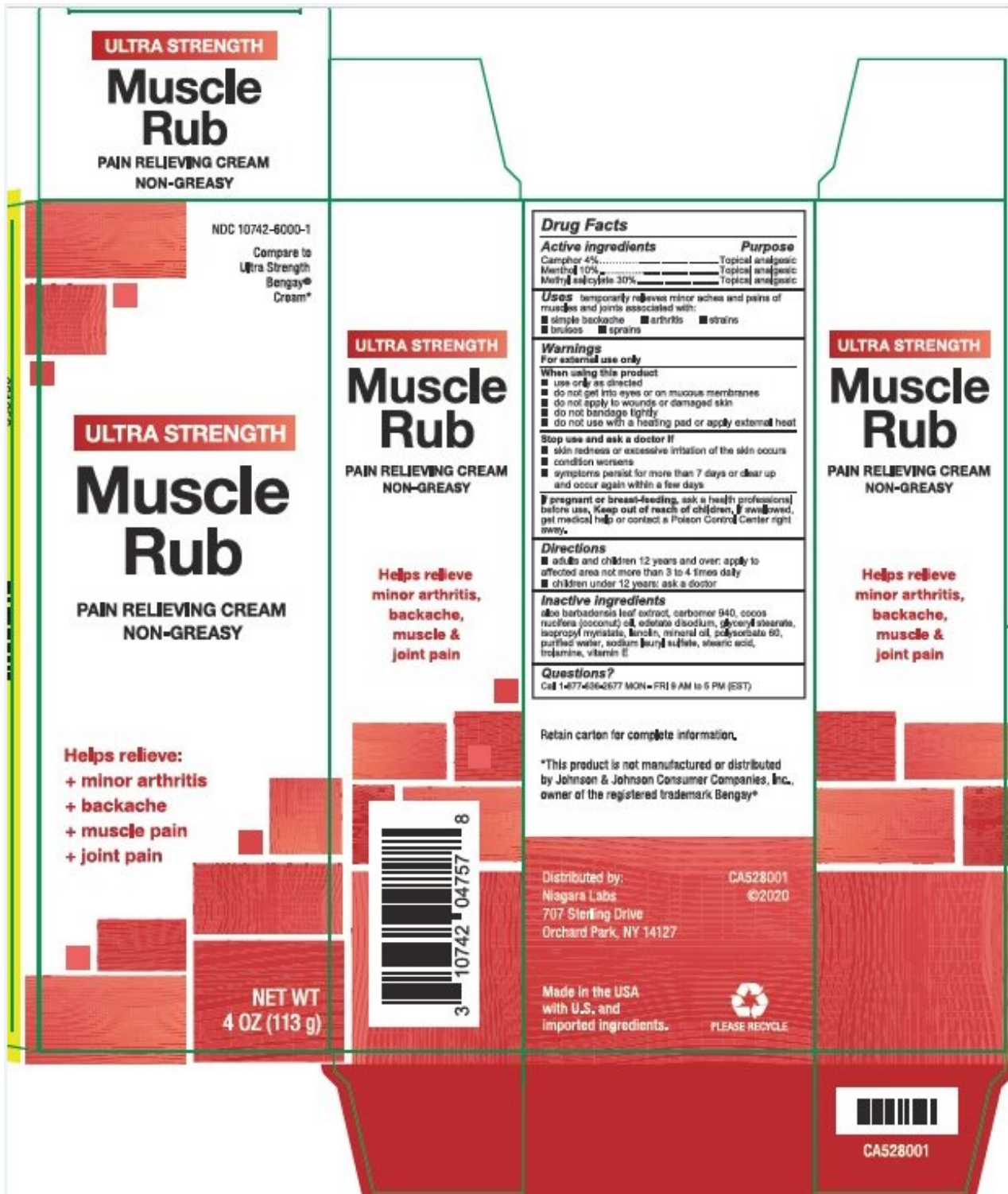
**Inactive ingredients**

aloe barbadensis leaf extract, carbomer 940, cocos nucifera (coconut) oil, edetate disodium, glyceryl stearate, isopropyl myristate, lanolin, mineral oil, polysorbate 60, purified water, sodium lauryl sulfate, stearic acid, trolamine, vitamin E

**Questions?**

Call 1-877-636-2677 MON - FRI 9 AM to 5 PM (EST)

**Package/Label Principal Display Panel**



## ULTRA STRENGTH MUSCLE RUB

camphor, menthol, methyl salicylate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-6000
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	40 mg in 1 g
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	100 mg in 1 g
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	300 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-6000-1	1 in 1 CARTON	03/08/2021	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/08/2021	

**Labeler** - The Mentholatum Company (002105757)**Registrant** - The Mentholatum Company (002105757)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
The Mentholatum Company		002105757	manufacture(10742-6000)

Revised: 2/2023

The Mentholatum Company